REMARKS

Paragraph 265 of the specification has been amended to update the status of the U.S. patent applications cited therein and to correct a typographical error.

Claim 1 has been amended so that it is now directed to an analyte sensor that comprises a working electrode and a biocompatible membrane disposed over the electrode. Support for this amendment may be found in the specification, for example, in paragraphs 206-209. Dependent Claims 2-23 and 135-139 have been amended to be made consistent with the amendments to Claim 1. Claims 24-26 have been amended to be made independent. Claims 1 and 24-26 have been further amended to recite that the terminal groups of the silicon and oxygen atom backbone are alkyl, alkenyl, aryl, or aralkyl moieties optionally substituted with one or more substituents selected from the group consisting of hydroxy, alkoxy, alkylsulfonyl, halogen, cyano, nitro, amino, and carboxyl. Support for this amendment may be found in the specification, for example, in paragraphs 158 and 199.

Claim 26 has been canceled without prejudice to pursuing it in a divisional, continuation, or continuation-in-part application.

New Claims 140-144 have been added. Claim 140 recites that the silicone composition is configured to resist diffusion of the analyte to an extent such that the sensor has a substantially linear response with respect to concentration of the analyte up to analyte concentrations of at least about 500 mg/dL. Support for this amendment may be found in the specification, for example, in paragraph 229. Claim 141 recites that wherein the hydrophile has a molecular weight from about 200 to about 1200 g/mol. Support for this amendment may be found in the specification, for example, in paragraph 136. Claims 142-144 recite that the silicone composition comprises from about 1 wt. % to about 19 wt. %, 10 wt. %, or 8 wt. % of the hydrophile, respectively. Support for this amendment may be found in the specification, for example, in paragraph 231.

No new matter has been introduced. Claims 1-25 and 135-144 are pending. The Applicants have carefully considered the Examiner's rejections, but respectfully submit that the claims are allowable for at least the following reasons.

Objection

Paragraph 265 was objected to because the status of the U.S. patent applications cited therein have not been updated. This paragraph has been amended to provide the updated status of the cited applications.

Rejections under § 102

Claims 1-12, 17-26, 138, and 139 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Kennedy (U.S. Patent No. 6,528,584). The Examiner argued that Kennedy discloses identical chemical compositions to those claimed and that the membrane disclosed in Kennedy would not be permeable to everything. Kennedy is directed to biocompatible membranes for encapsulating biological material. *See* Kennedy, column 1, lines 17-40. Kennedy does not disclose an analyte sensor comprising an electrode and a biocompatible membrane. Therefore, the Applicants respectfully submit that Claims 1-12, 17-23, 138, and 139 are not anticipated by Kennedy. Similarly, Claims 24 and 25, which are directed to a biosensor and drug delivery device, respectively, are not anticipated by Kennedy.

Furthermore, one of skill in the analyte sensor field would not be motivated to use the membranes disclosed in Kennedy with an analyte sensor. Kennedy discloses that a key feature of its membrane is that it is permeable to water (e.g., maximizes water swelling). *See* Kennedy, column 1, line 40-65 and column 13, lines 20-21. To this end, Kennedy teaches to include a high PEG content (specifically between 20 wt. % and 50 wt. %). *See* Kennedy, column 8, lines 35-43 and column 13, lines 20-24. Kennedy also teaches to use high molecular weight PEG (i.e., 4600 g/mol). *See* Kennedy, column 10, lines 16 and 65-67. Such high PEG content and size would render the membrane highly permeable to analytes in biological fluids (e.g., glucose—see Claim 139), making them unsuitable for use with an analyte sensor. As discussed in the instant specification, one goal in sensor design is to resist diffusion of the analyte such that it is rate limiting. The structure of the membrane disclosed by Kennedy (i.e., high PEG content) does not exhibit this property. Thus, it would not be obvious to use the membrane of Kennedy with an analyte sensor.

The Applicants also note that Kennedy does not disclose the chemical compositions claimed in New Claims 140-145. Specifically, the composition disclosed by Kennedy has a hydrophile with a molecular weight (i.e., 4600 g/mol) considerably outside of the range claimed

in Claim 141 of from about 200 to about 1200 g/mol. Kennedy also teaches to have a PEG content between about 20 wt. % and about 50 wt. %, which is outside of the ranges recited in Claims 142-144. For these additional reasons, the Applicants respectfully submit that Claims 140-145 are not anticipated by nor rendered obvious over Kennedy.

Claims 1-5, 7, 8, 10, 11, 17-19, 138, and 139 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Al-Lamee (2003-0059631). The Examiner argued that the chemical composition disclosed in Al-Lamee is the same as the claimed composition and that the Al-Lamee membrane binds heparin and does not allow it to diffuse. Al-Lamee discloses a membrane for coating a device with heparin that is in contact with circulating blood. *See* Al-Lamee, paragraphs 5-9. Al-Lamee does not disclose an analyte sensor comprising an electrode and a biocompatible membrane. Therefore, the Applicants respectfully submit that Claims 1-5, 7, 8, 10, 11, 17-19, 138, and 139 are not anticipated by Kennedy.

Furthermore, one of skill in the analyte sensor field would not be motivated to use the membranes disclosed in Al-Lamee with an analyte sensor. Al-Lamee discloses that its organopolysiloxane polymers are soluble in a lower alcohol (e.g., 2-propanol). *See* Al-Lamee, paragraph 15. Although Al-Lamee does not disclose the specific chemical composition of its polymers, solubility in a lower alcohol is indicative of significantly high hydrophile content such that it would not resist diffusion of an analyte (e.g. glucose—see Claim 139) to an extent suitable for use with an analyte sensor. In addition, the membrane in Al-Lamee, which binds heparin, cannot be said to resist diffusion of heparin such that it would be suitable for use in a heparin sensor. Stopping all diffusion of an analyte would prevent its detection by the sensor. Thus, it would not be obvious to use the membrane of Al-Lamee with an analyte sensor.

The Applicants also note that Al-Lamee does not disclose the chemical compositions claimed in New Claims 140-145. Al-Lamee does not disclose the molecular weight or amount of its hydrophilic component. For this additional reason, the Applicants respectfully submit that Claims 140-145 are not anticipated by nor rendered obvious over Al-Lamee.

Claims 1-12, 17, 19-26, 138, and 139 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Keogh et al. (U.S. Patent No. 4,260,725). The Examiner argued that the silicon composition in Keogh is the same as that recited in the claims. Keogh is directed to water absorbing contact lenses. *See*, Keogh, column 1, lines 9-13. Keogh does not disclose an analyte

sensor comprising an electrode and a biocompatible membrane. Therefore, the Applicants respectfully submit that Claims 1-12, 17, 19-23, 138, and 139 are not anticipated by Keogh. Similarly, Claims 24 and 25, which are directed to a biosensor and drug delivery device, respectively, are not anticipated by Keogh.

Furthermore, one of skill in the analyte sensor field would not be motivated to use the membranes disclosed in Keogh with an analyte sensor. Contact lenses are completely outside of the field of analyte sensors. Keogh does not provide any discussion of diffusion resistance. Accordingly, one of skill in the art would not be motivated to look to Keogh to solve problems associated with analyte sensors.

Claims 1-26 and 135-139 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Van Antwerp (U.S. Patent No. 5,777,060). The Examiner argued that the use of the term "substituted" rendered the claimed compositions broad enough to encompass the isocyanate and urethane linked hydrophile disclosed in Van Antwerp. The Applicants have amended the claims to recite that the terminal groups of the silicon and oxygen atom backbone are alkyl, alkenyl, aryl, or aralkyl moieties optionally substituted with one or more substituents selected from the group consisting of hydroxy, alkoxy, alkylsulfonyl, halogen, cyano, nitro, amino, and carboxyl. Thus, the allowed substitution on the terminal groups has been narrowed to one of only 8 chemical groups, none of which include an isocyanate or the large chemical group disclosed in Van Antwerp as being attached to a terminal end of a siloxane polymer. Accordingly, the Applicants respectfully submit that Claims 1-25 and 135-139 are not anticipated by Van Antwerp.

CONCLUSION

By the foregoing amendments and remarks, the Applicants respectfully submit that they have overcome the pending rejections and request a timely issuance of a Notice of Allowance.

No fees are believed due; however, please charge any fees that are determined to be due, including any fees for extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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